UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Master File No. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: United States ex rel. Edward West, et al. v. Ortho-McNeil Pharmaceutical, Inc. and Johnson & Johnson Civil Action No. 06-12299-PBS	

UNITED STATES' STATEMENT OF INTEREST IN RESPONSE TO DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION

The United States, the real party in interest in this action, submits this Statement of Interest pursuant to 28 U.S.C. § 517 to respond to certain arguments made by defendants in their motion to dismiss relator's First Amended Complaint. The United States remains the real party in interest in this matter, even where it has not intervened in the action. *United States ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.3d 220, 231 (1st Cir. 2004). In addition, because the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.,* is the United States' primary tool used to prosecute fraud on the government, it has a keen interest in the development of the law in this area and in the correct application of that law in this, and similar, cases.

The United States submits this brief to underscore that the public disclosure bar contained in the FCA does not apply to the allegations in this case in all the ways that defendants contend.

BACKGROUND

Relator Edward West filed this action in the United States District Court for the Northern District of Illinois under the *qui tam* provisions of the False Claims Act (FCA), 31 U.S.C. § 3730, which permits a private person to file an action on behalf of the United States. Under the FCA, a proper relator is entitled to share in the proceeds of the prosecution of the claims in his or her complaint, with the United States retaining, at a minimum, seventy percent of the proceeds of the action. The FCA requires that the relator file his or her action under seal, during which time the United States may evaluate the allegations and investigate the claims in the complaint so that it may decide whether to intervene in and take over the action. 31 U.S.C. § 3730(b)(2). On January 20, 2006, the United States notified the district court in Illinois that it was declining to intervene in the action. Even in declined matters, however, the United States remains the real party in interest as the suit is being brought on its behalf and it stands to recover the lion's share of any proceeds resulting from the action.

After the case was declined, relator filed a motion to transfer the action to the instant multi-district litigation (MDL). The MDL panel ordered the action transferred, but it severed the claims relating to off-label marketing and remanded those claims to the Northern District of Illinois. Defendants now move to dismiss the AWP-related claims pending in the instant MDL on jurisdictional grounds.

Relator's First Amended Complaint alleges that Ortho-McNeil reported inflated AWPs for two of its drugs, Levaquin and Ultram, and that Ortho-McNeil provided various sorts of remuneration to health care providers in order to induce those providers to prescribe defendants' drugs. Defendants seek dismissal of the First Amended Complaint on the grounds that, pursuant

to a jurisdictional bar contained in the FCA, this court lacks jurisdiction over relator's claims. The United States takes no position regarding the merits of relators's complaint. The United States submits this brief to clarify certain important points of law relating to the applicability of the public disclosure bar of the FCA.

ARGUMENT

Defendants argue in the motion to dismiss that under the FCA, 31 U.S.C § 3730(e)(4)(A), relator's action is barred. Under this provision, commonly described as "the public disclosure bar," courts have no jurisdiction over FCA actions if the actions are based upon allegations or transactions that have been publicly disclosed in criminal, civil or administrative hearings, certain government reports, audits or investigations, or in the news media unless the person bringing the action is an original source of the information.

The determination of whether a relator's complaint should be dismissed for lack of subject matter jurisdiction requires a three-step inquiry. The court must determine: (1) whether the allegations or transactions in the complaint have been publicly disclosed in a manner provided by the statute; (2) if so, whether the relator's suit is "based upon" those allegations or transactions;[1] and (3) if the answer to both of those questions is yes, whether the relator falls

[1] The majority of courts to have construed this provision have held that an action is "based upon" a public disclosure when a relator's allegations are similar to those that have been publicly disclosed regardless of where the relator obtained his information, and the United States believes that that is the proper application of the provision. The First Circuit has not addressed the "based upon" language, and district court decisions in this circuit have been split on the issue. *Compare United States ex rel. O'Keefe v. Sverdup Corp.,* 131 F. Supp. 2d 87, 92 (D. Mass. 2001) (adopting majority view) *with United States ex rel. Rost v. Pfizer, Inc.*, 446 F. Supp. 2d 6, 19 (D. Mass. 2006) (adopting minority view).

within the "original source" exception to the jurisdictional bar.[2] *United States ex rel. O'Keefe v. Sverdup Corp.,* 131 F. Supp. 2d 87, 91 (D. Mass. 2001). If the relator does not qualify as an original source, the action must be dismissed for lack of jurisdiction.

Defendants contend that relator's AWP allegations are barred because the same allegations were publicly disclosed in the context of this MDL, in government reports discussing drug pricing, and in the Medicare Modernization Act (MMA). Brief at 7; Reply Brief at 7, 9.[3] The United States submits that the government reports alluded to by defendants and the MMA do not constitute public disclosures under the statute because they do not contain the allegations or transactions of the instant lawsuit.

As this court has recognized, the widely accepted framework for determining whether a public disclosure of the allegations or transactions has occurred was set forth in *United States ex rel. Springfield Terminal Railway Co. v. Quinn*, 14 F.3d 645, 655 (D.C. Cir. 1994). *O'Keefe,*

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[2] The FCA provides that a relator who seeks to avoid the jurisdictional bar must show that he has "voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B). Several courts have held that to qualify as an original source, a relator must provide his information to the government prior to the public disclosure as opposed to simply prior to his filing suit, and the United States believes that that interpretation is the correct one. However, the First Circuit has not yet addressed this issue, and there is at least one district court decision in this circuit holding otherwise. *Rost*, 446 F. Supp. 2d at 23.

[3] It is not clear from defendants' briefs what pleading in the MDL constitutes the public disclosure on which their motion rests. Defendants cite both the master class action complaint and complaint by the State of Nevada as public disclosures. Brief at 7; Reply Brief at 2-3. However, although the master class action complaint contains allegations against other Johnson & Johnson companies, it does not appear to contain allegations against Ortho-McNeil or Ortho-McNeil's drugs Levaquin and Ultram. Likewise, although the Nevada complaint appears to contain allegations against Johnson & Johnson, including "Mc-Neil PPC," it is not clear, at least from defendants' briefs, whether the Nevada complaint contains allegations about Ortho-McNeil, Levaquin, and Ultram or whether, if the complaint does contain such allegations, the amended Nevada allegations preceded the filing of relator West's action in 2003.

131 F. Supp. 2d at 94. As set forth in *Springfield Terminal*, "the term "allegation" connotes a conclusory statement implying the existence of provable supporting facts. "The term "transaction" suggests an exchange between two parties or things that reciprocally affect or influence each other." 14 F.3d at 653-54. Therefore, "if X + Y = Z, Z represents the *allegation* or fraud and X and Y represent its essential elements." *Id.* At 654. "Congress sought to prohibit *qui tam* actions *only* when either the allegation of fraud or the critical elements of the fraudulent transaction themselves were in the public domain." *Id.* "When either of these conditions is satisfied, the government itself presumably can bring an action under the FCA and there is no place in the enforcement scheme for *qui tam* suits." *Id.* Thus, absent the public disclosure of an allegation of fraud, both of the critical elements – "a misrepresented state of facts *and* a true state of facts" – must be in the public domain. *Id.* at 655. The presence of one or the other, but not both, cannot be expected to set government investigators on the trail of fraud. *Id.* at 656.

As the *Springfield Terminal* court further observed, "[k]nowledge of the allegedly misrepresented state of affairs – which does not necessarily entail knowledge of the fact of misrepresentation – is *always* in the possession of the government." *Id.* In other words, through the very act of claims being presented to it, the government almost always learns at least some of the misrepresented facts, and when the government publicly acknowledges that such claims were presented, one of the essential elements of the fraud (*i.e.*, the false information) may be in the public domain. However, it is only when the true state of affairs – that the services in fact were not rendered, the amount billed was inflated, or there was a kickback that made the claim ineligible for payment – also are in the public domain that both the X + Y may be present and the jurisdictional bar will be triggered. *Id.*

Under the *Springfield Terminal* test, it is clear that the government reports on drug pricing vaguely referred to by defendants do not constitute public disclosures of the allegations or transactions here. First, defendants do not identify a single report specifically mentioning the drugs that are the subject of the instant action. Second, even generally speaking, the reports do not contain the essential elements of a fraud (both X and Y), and certainly do not contain an allegation of fraud (Z). The government reports merely observe that providers often can purchase certain drugs for less than AWP. At most, the reports reflect a concern about the government's use of published AWPs to set drug reimbursement to providers. Thus, to the extent the government reports place anything in the public domain, it is, at most, some information about the misrepresented state of affairs (the false prices that drug companies reported) as to a limited number of drugs and accordingly, not even half of the story. Moreover, the true state of affairs, that defendants (and other drug companies) may have (1) reported AWPs for their drugs that were inflated for the purpose of creating artificially large spreads and (2) reported AWPs that *no one* paid, clearly was not placed in the public domain by virtue of the government reports mentioned by defendants.[4]

As to the MMA itself, defendants' public disclosure argument makes even less sense. The Act, of course, does not mention the drugs at issue in this case, much less contain an allegation of fraud as to Ortho-McNeil.

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[4] Notably, in prior AWP matters in this district, defendants like Ortho-McNeil have offered these types of government reports for a variety of purposes, and the courts have properly ascribed little to no weight to them. As Judge Stearns observed, "[t]he recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct." *In re Lupron Marketing and Sales Practices Litigation*, 295 F. Supp. 2d 148, 168 n.19 (D. Mass. 2003).

Accordingly, the government reports and the MMA do not constitute public disclosures of the allegations or transactions of the instant suit and do not trigger the application of the jurisdictional bar here.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' STATEMENT OF INTEREST IN RESPONSE TO DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Jamie Ann Yavelberg
Dated: August 16, 2007 Jamie Ann Yavelberg